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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,652	11/25/2003	Glenn R. Gibson	N-32809A	7110
1095	7590	08/22/2007		
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			EXAMINER BARHAM, BETHANY P	
			ART UNIT 1615	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/721,652	GIBSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bethany P. Barham	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-8,10,11 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-8,10,11 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt is acknowledged of the Applicants' Response and Amended Claims filed on 07/31/2006 and 8/13/2007. Receipt is also acknowledged of Applicants' Compliance with the Sequence Rules. Claims 2, 4, and 9 are cancelled (from 07/31/2006 response). Claims 12-25 remain cancelled without traverse (from 02/12/2007 response). Claims 1, 3, 5-8, 10-11, and 26 are pending in this action. Claims 1, 3, 5-8, 10-11 and 26 are rejected.

Applicants have repeatedly stated that the cancellation of claims 18-25 was in error (07/31/2006 and 8/13/2007). The Examiner has also addressed that the cancellation of the claims by applicant in the response on 02/12/2007 and as such claims 18-25 remain cancelled as requested in the response filed by applicant on 12/12/2005.

Upon further consideration the Examiner acknowledges that newly added claim 26 was not properly rejected in the response sent on 02/12/2007, therefore this supplemental action is being sent to address newly added claim 26 from the 07/31/2006 claim set.

### MAINTAINED REJECTIONS (from 02/12/2007)

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lesens et al US 6,399,124 B1.

Lesens et al teaches the limitations of claims 1, 3 and 5:

- Lesens et al teaches composition comprising fermentable fibers specifically promoting the growth, in the intestinal tract, of the lactic acid bacteria contained initially in the ice cream for the treatment and/or prevention of gastrointestinal disorders, for strengthening the immune system, or for increasing the absorption of minerals (abstract).
- Lesens et al teaches the composition contains prebiotic fibers (abstract), which may be of a protein or saccharide nature, chosen for example from vegetable pectins, chito-, fructo-, gentio-, galacto-, isomalto-, manno- or xylo oligosaccharides, etc (col. 4, lines 44-47; and claim 2). The preferred galacto-oligosaccharides comprise a saccharide part consisting of 2 to 5 repeating units and preferred fructooligosaccharides are inulin-oligofructoses extracted from chicory which may comprise, for example, 1-9 repeating units (col. 4, lines 56-64; and claim 26). Examples 1, 4 and 5 specifically teach edible compositions, coatings and decorations containing galactooligosaccharide P7L, Raftilose L30 and Actilight 950P.
- The composition of Lesens et al teaches that the quantity of fibers in the dessert may contain from 0.1 to 20% of such fibers (by weight relative to dry matter

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content), and that a single dessert may be designed to provide up to a maximum of 10 g of fiber per dessert (col. 5, lines 15-25).

- Examples 4-5 of Lesens et al teach a cone made of Raftilose L30 (Table 7) or wafer dough of galactooligosaccharide P7L, respectively; and a decoration or coating such as that of Table 3 (galactooligosaccharide P7L) or Table 4 (Raftilose L30). Such a ratio would yield a weight ratio of 1.56 FOS:GOS in the single food composition.
- Example 4 teaches 1.1 g fibers are provided per ice cream cone, while Example 6 teaches 2.1 g of fiber from the sandwich. Claim 9 of Lesens et al teaches that about 0.1 to about 10% of the frozen dessert comprises fibers.

Lesens et al teaches the limitations of claims 6-8 and 11:

- Lesens et al teaches compositions wherein the edible support alone comprises between about 1 to about 60% milk, between about 0.5 to about 5% of animal or vegetable proteins, between about 0.1 to about 10% fibers, between about 15% to about 30% sucrose and between about 2% to about 20% fat, by weight (claim 9). Examples 1 and 2 teach that a consumption of 200 mL or 100 g of ice cream per day provides proper dietary supplement. And it is the examiners position that all examples of Lesens et al are compositions that are ready-for-consumption and high in calories.

Lesens et al anticipates the instant applications claims 1, 3, 5-8 and 11.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesens et al US 6,399,124 B1.

Lesens et al teach the limitations of claims 1, 5, and 10:

- Lesens is taught above and claims 1 and 5 are taught above.
- Lesens et al teaches compositions wherein the edible support alone comprises between about 1 to about 60% milk, between about 0.5 to about 5% of animal or vegetable proteins, between about 0.1 to about 10% fibers, between about 15% to about 30% sucrose and between about 2% to about 20% fat, by weight (claim

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9). But examples 4-6 also teach compositions comprising flour, which provides a significant amount of carbohydrates (52g - 62g flour/100g total weight).

- Lesens et al does not teach a composition of claim 10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Lesens et al to make a composition of FOS, GOS, proteins, carbohydrates, and fats, and one of ordinary skill in the art would be motivated to experiment and optimize values to obtain workable ranges. As stated in MPEP 2144.05: *"[W] here the general conditions of a claim are disclosed in prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."*

Claims 1, 3, 5, 7-8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al and Boehm et al and Rigo et al in view of Lesens et al US 6,399,124 B1.

Moro et al and Boehm et al and Rigo et al in view of Lesens et al teach the limitations of claims 1, 3, 5, 7-8, and 10-11:

- Moro et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See pages 291, 294 and Table 1). According to Moro et al., the oligosaccharide mixture can comprise between the 90% GOS and 10% FOS (page 292). This satisfies the weight ratio of FOS:GOS of about 0.01 to about 50. According to Table 1, the oligosaccharide mixture can comprise between about

0.05 to about 40% by weight, based on the total formulation. As formulated, it is the examiner's position that the formula advanced by Moro et al. is both "nutritionally complete" and "ready-for-consumption."

- Boehm et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See page F179 and Table 1). According to Boehm et al., the oligosaccharide mixture can comprise between the 90% GOS and 10% FOS (page F178). According to Table 1, the oligosaccharide mixture can comprise between about 0.05 to about 40% by weight, based on the total formulation. As formulated, it is the examiner's position that the formula advanced by Boehm et al. is both "nutritionally complete" and "ready-for-consumption."
- Moro et al and Boehm et al do not teach a composition comprising more than about 1 g of protein in 100 kcal of claim 7.
- Rigo et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See Table 1). According to Table 1, the oligosaccharide mixture can comprise between about 0.05 to about 40% by weight, based on the total formulation, and over 1% of protein can be present per 100 kcal. As formulated, it is the examiner's position that the formula advanced by Rigo et al. is both "nutritionally complete" and "ready-for-consumption."
- Moro et al, Boehm et al, and Rigo et al do not teach the exact percentages of ingredients and ratio of GOS to FOS as claimed.



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- Lesens et al is taught above. Lesens teaches the ratio and percentages.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Moro et al and Boehm et al and Rigo et al in view of Lesens to make a composition comprising a mixture of prebiotic fibers such as FOS and GOS, and other ingredients for consumption. One of ordinary skill in the art would be motivated to experiment and optimize values to obtain workable ranges to treat those with gastrointestinal disorders, to promote the growth, in the intestinal tract, of the lactic acid bacteria, also for strengthening the immune system, or for increasing the absorption of minerals. As stated in MPEP 2144.05: *"[W] here the general conditions of a claim are disclosed in prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."* Because the exact formulation and portion of a baby formula, nutritional supplement, or other edible composition is determined by age, size, health, and other variables it would be reasonable for one of ordinary skill in the art to experiment and optimize the values set forth in Moro et al and Boehm et al and Rigo et al in view of Lesens et al in order to obtain a composition capable of delivering the appropriate amount of nutrients to the patient.

Claims 1, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesens et al US 6,399,124 B1 in view of Van Leeuwen et al US 2003/0138476 A1. Lesens et al in view of Van Leeuwen et al teach the limitations of claims 1, and 26:

- Lesens et al is taught above and claim 1 is taught above. Lesens et al teaches composition comprising fermentable fibers specifically promoting the growth, in the intestinal tract, of the lactic acid bacteria contained initially in the ice cream for the treatment and/or prevention of gastrointestinal disorders, for strengthening the immune system, or for increasing the absorption of minerals (abstract).
- Lesens et al teaches the composition contains prebiotic fibers (abstract), which may be of a protein or saccharide nature, chosen for example from vegetable pectins, chito-, fructo-, gentio-, galacto-, isomalto-, manno- or xylo oligosaccharides, etc (col. 4, lines 44-47; and claim 2). Examples 1 and 2 teach that a consumption of 200 mL or 100 g of ice cream per day provides proper dietary supplement.
- Lesens et al does not teach including glutamine, but does teach compositions containing milk, animal or vegetable proteins, which are known to contain glutamine (claim 9).
- Van Leeuwen et al teach nutritional preparations such as baby food or enteral food (abstract) which include prebiotics such as fructo-oligosaccharides and galacto-oligosaccharides and further glutamine or an equivalent such as is known in the art (pg. 1, [0013-0014], pg. 2, [0017]). Further, Van Leeuwen et al claims a nutritional preparation as a nutritional preparation with also contains glutamine or equivalent thereof and further prebiotics such as galacto-oligosaccharides and fructo-oligosaccharides (claims 1-3, 8, and 12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the compositions as taught by Lesens et al with glutamine as taught by Van Leeuwen et al. One of ordinary skill in the art would have been motivated to combine the teachings since both teach nutritional compositions that help the intestinal tract and provide fibers such as prebiotics (galacto-oligosaccharides and fructo-oligosaccharides). As such one would have a reasonable expectation of success in adding the glutamine of Van Leeuwen et al to the compositions of Lesens et al, especially since Van Leeuwen et al teaches that products which are rich in glutamine include vegetable proteins (pg. 1, [0005]), as is already taught by Lesens et al (claim 9).

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 3, 5-8, 10-11 and 26 have been considered but not persuasive and are moot in view of the new grounds of rejection necessitated by applicants' amendments. Applicants argue that Lesens et al does not teach compositions comprising galacto-oligosaccharides and fructo-oligosaccharides. The Examiner respectfully disagrees, as Lesens et al teach both galacto-oligosaccharides and fructooligosaccharides are preferred (col. 4, lines 56-64; and claim 26). Furthermore, Lesens et al teaches in examples 1, 4 and 5 ice cream put into a cone or wafers containing either (galacto-oligosaccharides or fructo-oligosaccharides) that is coated with composition of Table 2 (containing galacto-oligosaccharides) or Table 3 (containing galacto-oligosaccharides) and decorated with a topping of Table 4 containing fructooligosaccharides. Lesens et al further claims fibers of between about

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0.1 to about 10% including fibers like galacto-oligosaccharides and fructo-oligosaccharides (claims 1-2, and 9) and as such that these fibers are useful for promoting the growth of the lactic acid bacteria in a human intestinal tract. Lesens et al anticipates and/or renders obvious the instant claims 1,3,5-8 and 10-11.

Furthermore, Applicant argues that the prior art does not teach synergistic effect of FOS and GOS, however Lesens et al does teach that the edible composition containing the fibers (FOS and GOS) promote the growth of the lactic acid bacteria in a human intestinal tract (abstract, claim 1) and as such proves that these fibers enhance lactic acid bacteria growth. The property or function of promoting lactic acid bacteria by ingestion of FOS and GOS are not separable from the structure of FOS and GOS as taught by Lesens et al. Also, Boehm et al teaches that the combination of FOS and GOS promotes beneficial intestinal bacteria in a synergistic way so that lactobacilli can grow (pg. F178, last paragraph and Abstract "conclusion"). Moro et al teaches that the optimal dosage of the FOS and GOS mixture are is 0.8 g/dL which produces a more pronounced bifidogenic effect than 0.4 g/dL, which indicates a synergistic effect of FOS and GOS (pg. 294, last paragraph-pg. 295 end); while Moro et al teaches that there was no difference in the dosages (0.4 or 0.8 g/dL) for the Lactobacilli, but that the number of Lactobacilli was significantly higher (at day 2 of the 28 day study) for both supplemental groups than the placebo group (pg. 293, last paragraph-pg. 294, lines 1-2). Rigo et al teaches that the use of prebiotics ("material and methods" uses a mix of FOS and GOS) resulted in a rapid and significant increase in the percentage of endogenous bifidobacteria and the ability to maintain a stable intestinal flora (pg. 39, summary

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"conclusion"). As such it is the examiners opinion that the art supports the synergistic effect of FOS and GOS in the growth of intestinal bacteria such as Lactobacilli. As such the rejections of record are hereby maintained.

### ***Conclusions***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Correspondence***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany P. Barham whose telephone number is 571-272-6175. The examiner can normally be reached on M-F from 8:30am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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